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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,733	03/04/2004	Felix West Fenter	ANDEV-100	5299
35777 7590 03/12/2007 SHERMAN & ASSOCIATES 415 NORTH ALFRED STREET ALEXANDRIA, VA 22314			EXAMINER BACHMAN, LINDSEY MICHELE	
			ART UNIT	PAPER NUMBER
			3734	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/791,733	Applicant(s) FENTER ET AL.	
	Examiner Lindsey Bachman	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 and 42-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-41 is/are rejected.
- 7) ☐ Claim(s) 24-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11-1-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the election/restriction response filed on 20 November 2006.

Election/Restrictions

1. Applicant's election with traverse of Invention III (Claims 24-41) in the reply filed on 20 November 2006 is acknowledged. Arguments follow below:

First and Second Restriction (I & II; I & III)

2. Applicant argues that the combination (Invention I – independent claim 1) requires the particulars of the subcombination (Invention II – independent claim 17 or Invention III – independent claim 24). Applicant states that the particulars are present in Claim 2. This argument is moot because the Claim 2 is a dependent claim on Claim 1. Claim 1 stands alone and therefore the device does not require the particulars of the subcombination.

Third Restriction (I & IV)

3. Applicant argues that the combination (Invention I – independent claim 1) requires the particulars of the subcombination (Invention IV – independent claim 42). Applicant states that the particulars are present in Claim 12. This argument is moot because the Claim 12 is a dependent claim on Claim 1. Claim 1 stands alone and therefore the device does not require the particulars of the subcombination.

Fourth Restriction (II & III)

4. Applicant argues that both Invention II (Claim 17) and Invention III (Claim 24) contain a mechanical actuator means. Examiner maintains that Invention II is a

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subcombination of Invention III because Invention II is meant for use with Invention III. For example, Claim 17, lines 2-3: "...a manipulatable wand *adapted to operate* a self-contained anastomosis appliance and applicator *attached thereto*..." Claim 17 does not claim the anastomosis appliance and applicator, only that that wand is capable of use with it.

Fifth Restriction (II & IV)

5. Applicant argues that Invention II requires the particulars of Invention IV, as clarified by the reiteration of Claim 17 with emphasis on pages 14-15 of Applicant's response filed on 20 November 2006. Examiner argues that the language of Claim 17 only requires that the wand is capable of being used with the anastomosis appliance and applicator as shown by the term "adapted to" in line 1 of Claim 17. The anastomosis appliance and applicator are not positively claimed in Claim 17.

Sixth Restriction (III & IV)

6. Applicant argues that the Invention III and IV both contain a housing containing a transmission portion and an appliance applicator portion. Examiner agrees however, Invention IV contains a drive mechanism and Invention III does not. Therefore, the combination does not require the particulars of the subcombination. Further, the subcombination has utility by itself as a blood vessel gripper.

The requirement the first through fifth restrictions is still deemed proper and is therefore made FINAL.

7. Claims 1-23 and 42-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

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generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 20 November 2006.

Drawings

8. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings contain copy machine marks (37 CFR 1.84(e)), the numbers are not plain and legible (37 CFR 1.84(p)), the scale of some of the drawings is not large enough to show detail, especially when reduced to two-thirds in reproduction (especially, but not limited to, Figures 27d-27h) (37 CFR 1.84(k)).

Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

9. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the transmission portion (Claim 24), the inflatable means (Claim 24), the anastomosis connecting means (Claim 24), the gripping connectors (Claim 24), the mechanical actuator means (Claim 24), the transmission means (Claim 24), the sequentially operable mechanism (Claim 24), and the wand positioning means (Claim 24) must be shown or the feature(s) canceled from the claim(s). Due to the large number of items missing from the drawings, Examiner has only indicated missing subject matter in independent claim 24.

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Applicant's cooperation is requested to locate and correct additional features missing or not labeled in the drawings. No new matter should be entered.

10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

11. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The

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abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

12. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

13. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the terms "transmission portion" (Claim 24), "inflatable means" (Claim 24), "anastomosis connecting means" (Claim 24), "gripping connectors" (Claim 24), "mechanical actuator means" (Claim 24), "transmission means" (Claim 24), "sequentially operable mechanism" (Claim 24), and "wand positioning means" (Claim 24) are not used in the specification. Due to the large number of items missing from the specification, Examiner has only indicated missing subject matter in independent claim 24. Applicant's cooperation is requested to locate and correct additional features missing from the specification.

14. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Content of Specification

- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

15. Claims 24-41 are objected to because of the following informalities: The claims do not contain line indentations to segregate the plurality of elements presented in the claims (see underlined portion above). Appropriate correction is required.

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claim 29 states that the anastomosis connecting means further comprises "gripping connector holder" in line 4. However, Claim 24 also claims that the anastomosis connecting means contains a "holder for gripping connectors" in lines 17-18. It is unclear if Applicant is claiming a single holder, or two separate holders.

Clarification is required.

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19. Claim 37 recites the limitation "the upper edge" in line 5. There is insufficient antecedent basis for this limitation in the claim.

20. Claim 39 recites the limitation "said curved face portion" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang, et al. (US Patent 6,699,177) in view of Kayan (US Patent 6,436,118).

24. Wang'177 teaches an anastomosis apparatus that contains an anastomosis appliance and applicator (AAA) (300) that contains a housing (302) (column 19, lines 17-23) which contains a transmission portion that contains gears (tubes 712, 716 with notches 750 for engaging) that are adapted to engage with the wand gears (column 20,

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lines 53-57). The AAA also contains an anastomosis/applicator portion for receiving portions of the blood vessels. The anastomosis/applicator portion contains a sequentially operable mechanism that includes an anastomosis connecting means with a plurality of gripping members (306, 308, Figures 9 and 10(all) as well as labeled portions in Figures 13-15), holders (312) for the gripping connectors, and translation means (350, 352, 354, 356, 358) that control the gripping members and allow the gripping members to bring the blood vessels into contact (column 19, lines 34-59). Further, Wang'177 teaches an manipulatable wand (400) that can be connected to a power supply (46) (column 19, lines 60-64; column 21, lines 34-41); the device also contains a mechanical actuator means (506, 508, 510); a transmission means (700); an AAA interface (tubes 618, 620 with notches 626) that engage with the anastomosis/applicator portion (column 20, line 58 to column 21, line 12). Further, Wang'177 teaches wand positioning means (50, 52) to provide gross and fine positioning of the wand and AAA (column 7, lines 17-56); and computer control means (column 6, lines 35 to column 7, line 5).

25. Wang'177 shows that the articulating members can be used for everting blood vessels (Figures 9 and 10(all)); however Wang'177 does not teach that inflatable means can be used for this.

26. Kayan'118 teaches that it is preferable to use balloons, rather than mechanical probes, for everting blood vessels when performing anastomosis procedures because balloons are less traumatic to the vessel (column 2, lines 1-18). Since Wang'177 discloses that his device can be used for anastomosis procedures (column 5, lines 33-

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43) and that different tools, (such as those shown in Figures 27-30; column 21, line 34-column 22, line 54) can be attached to the distal end of the arms depending on the procedure being carried out. In light of this, it would have been obvious to one skilled in the art at the time the invention was made to place inflatable members for everting blood vessels, as taught by Kayan'118, at the distal end of the arms taught by Wang'177, in order to evert blood vessels when performing an anastomosis on a patient because balloons are less traumatic to the vessels than traditional everting mechanisms.

27. Claim 25: Wang'177 teaches that the transmission portion comprises shaft member (351, 353) that is attached to gears and extends into the appliance and applicator portion (Figure 21; column 20, line 58 to column 21, line 27). Further, the shaft members are in contact with means to engage and drive the sequentially operable mechanism in response to rotation by the interface (column 19, lines 34-59).

28. Claim 26: Kayan'118 teaches that the inflatable member is an inflatable balloon (70) with a holder assembly (21) that inflates away from the holder to evert blood vessels (column 3, lines 8-12). Further, Kayan'118 discloses an inflation syringe (column 7, lines 63-67) that is capable of inflating and deflating a balloon multiple times during a single use (column 3, lines 13-16). It would be obvious to control the balloons with the shaft members taught by Wang'177 above because this would automate the anastomosis process and allow the entire procedure to be performed remotely. Further, Kayan'118 does not teach the use of a separate balloon for everting each blood vessel used in an anastomosis. However, it would be obvious to use repeat the procedure

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done with one balloon when everting a vessel with a second, different balloon on the second blood vessel.

29. Claim 27 and 28: Kayan'118 teaches that the balloon can be shaped according to the procedure being formed. For this reason, it would be obvious to make the balloons identical when performing an end-to-end anastomosis because the portions of the two vessels being operated on are identical and different when performing an end-to-side anastomosis because the portions of the vessels being operated on are different and have different eversion requirements.

30. Claim 36, 37, 38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang'177 in view of Kayan'118, as applied to Claim 24, in further view of Hinchliffe et al (US Patent 5,833,698).

31. Wang'177 and Kayan'118 teach the limitations of Claims 29-35 except for the use of holder/ejector assemblies.

32. Hinchliffe'698 teaches the use of a holder/ejector assembly (Figure 3a) that contains a annular gripping connector holder (100a, 100b), a two part gripping connector (78a, 78b), a gripping connector ejector (38) (column 9, lines 38-47), and a translation mechanism (24). Hinchliffe'698 does not teach two devices, however it would be obvious, especially when performing an end to end anastomosis to have two identical devices each attached to an arm taught by Wang'177 in order to perform simultaneous work on a vessel, rather than working on the vessels in succession. Further, it would be obvious to replace the distal ends of the arms taught by Wang'177

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with the tools taught by Hinchliffe'698 because Hinchliffe teaches components known in the art to those who perform anastomosis procedures.

33. Claim 30: Hinchliffe'698 teaches that the annular holders are holder are separable (see Figure 3a).

34. Claim 31: Hinchliffe'698 teaches that that the translation means controls a screw shaft (58) that operates through the holder/ejector assembly (see Figures 3, 3a).

35. Claim 32 and 33: Hinchliffe'698 teaches that the holder/ejector contains a semi-circular and two quarter circular sections (see Figure 3a) and the appliance applicator contains a guide means (14).

36. Wang'177 and Kayan'118 teach the limitations of Claim 36 except for the use of tines on the gripping connectors.

37. Claim 36: Hinchliffe'698 teaches a body (378, Figure 26) with tines (334) and a connecting structure (350). It would have been obvious to modify the device taught by Wang'177 and Kayan'118 with the distal end taught by Hinchliffe'698 because it is a well-known structure for performing an anastomosis. The device taught by Wang'177 and Kayan'118 is extensively described in a grafting procedure, but it is disclosed that the device can be used for anastomosis procedure. Further, Wang'177 discloses that the tools at the ends of the arms can be interchanged depending on the needs of the surgeon and procedure being performed. For this reason, it would have been obvious to one skilled in the art at the time the invention was made to use the device taught by Hinchliffe'698 with the device taught by Wang'177 and Kayan'118 in order to remotely and robotically perform an anastomosis.

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38. Claim 37 and 41: Hinchcliffe'698 teaches that the body contains a forward face portion (354) with a radius that corresponds to the blood vessel being anastomosed. The tines extend outward and upward (Figure 26). The connecting structure extends forward of forward face portion over at least one tine (see Figure 26). It would have been obvious to one skilled in the art at the time the invention was made to use the device taught by Hinchcliffe'698 with the device taught by Wang'177 and Kayan'118 in order to remotely and robotically perform an anastomosis.

39. Claim 38: Hinchcliffe'698 teaches that the connecting structure has a male connector element (334) and a female connector element (380) (Figure 26, 26a, 27). It would have been obvious to one skilled in the art at the time the invention was made to use the device taught by Hinchcliffe'698 with the device taught by Wang'177 and Kayan'118 in order to remotely and robotically perform an anastomosis.

40. Claim 39: Hinchcliffe'698 teaches that the gripping connectors can also be an extension of the body-extending forward (Figure 1a, 2a). Further, there is a locator pin (32). Regarding the limitations of the other connecting structure, see Claim 39. It would have been obvious to one skilled in the art at the time the invention was made to use the device taught by Hinchcliffe'698 with the device taught by Wang'177 and Kayan'118 in order to remotely and robotically perform an anastomosis. It would have been obvious to one skilled in the art at the time the invention was made to use the device taught by Hinchcliffe'698 with the device taught by Wang'177 and Kayan'118 in order to remotely and robotically perform an anastomosis.

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41. Claim 40: Hinchliffe'698 teaches that the connecting structure is a mirror image pairs of extensions on each gripping connector (see separate connecting structures in Figure 26). The structures interdigitate and are held together when the gripping connectors join (see elements 334 and 380). It would have been obvious to one skilled in the art at the time the invention was made to use the device taught by Hinchliffe'698 with the device taught by Wang'177 and Kayan'118 in order to remotely and robotically perform an anastomosis.

Allowable Subject Matter

42. Claims 34-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: Claims 34-35 are allowable because the art of record does not disclose the combination of a dual-balloon structure that everts vessels and a cutting blade along with a vessel connecting device.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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